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Jong Lim

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EXAMINER

YOUNG, MICAH PAUL

ART UNIT

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Please find below and/or attached an Office communication concerning this application or proceeding.

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**BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES**

Application Number: 10/623,481
Filing Date: July 18, 2003
Appellant(s): LIM ET AL.

Judy Mohr
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed 12/17/10 appealing from the Office action mailed 2/19/10.

Art Unit: 1618

(1) Real Party in Interest

The examiner has no comment on the statement, or lack of statement, identifying by name the real party in interest in the brief.

(2) Related Appeals and Interferences

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The following is a list of claims that are rejected and pending in the application:

Claims 1-18 are currently pending and finally rejected.

(4) Status of Amendments After Final

The examiner has no comment on the appellant's statement of the status of amendments after final rejection contained in the brief.

(5) Summary of Claimed Subject Matter

The examiner has no comment on the summary of claimed subject matter contained in the brief.

(6) Grounds of Rejection to be Reviewed on Appeal

The examiner has no comment on the appellant's statement of the grounds of rejection to be reviewed on appeal. Every ground of rejection set forth in the Office action from which the appeal is taken (as modified by any advisory actions) is being maintained by the examiner except for the grounds of rejection (if any) listed under the subheading "WITHDRAWN

Art Unit: 1618

REJECTIONS.” New grounds of rejection (if any) are provided under the subheading “NEW GROUNDS OF REJECTION.”

(7) Claims Appendix

The examiner has no comment on the copy of the appealed claims contained in the Appendix to the appellant’s brief.

(8) Evidence Relied Upon

6,171,618

JOHNSON et al

1-2001

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

3. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various

Art Unit: 1618

claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

4. Claims 1-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over the disclosure of Johnson et al (USPN 6,171,618 hereafter '618).

5. The '618 patent is drawn to a method of making a combination dosage form comprising two separate drugs having different release rates (abstract). The first drug (the controlled release agent) is released so that at least 75% of the drug is released over a period of 4-36 hours (col. 3, lin. 10-15). The first drug is formed into a core with a solid matrix material such as microcrystalline cellulose and hydroxypropyl cellulose (col. 17, lin. 50-55). The drug material is dispersed in the solid matrix (col. 6, lin. 57-65). The core is then coated with a solution of a polymer matrix not comprising a drug and can fully encompass the core or cover sections having pores (col. 18, lin. 5-10; col. 10, lin. 8-68). The pores measure less than 50 microns, meaning the drugs must measure far below 50 microns (col. 10, lin. 55-60). The pores form after administration and as such do not allow for interaction between the coating layer drugs and the drugs of the matrix core. The polymer matrix comprises polyvinyl alcohol (col. 9, lin. 25). The resultant coated core is further coated with a drug formulation (col. 18, lin. 30-40). The tablets are dried leaving a solid two drug controlled release agent with the top drug formulation releases immediately while the inner coated drug releases slower (examples). Solvents include water,

Art Unit: 1618

ethanol and acetone (example). The weight ratio of the polymeric film to the unitary body (core) is approximately 0.16:1 (example 2).

6. The reference differs from the instant claims in disclosures of the ratio of unitary dosage from to the polymeric film, however this limitation is well within the limits of one of ordinary skill in the art to manipulate and arrive at through routine experimentation. The reference is further silent to the specific amount of first drug is release within the first hour. Although 75% of the drug is release over a period of 4-36 hours, there are no explicit disclosures for the first hour. However it is the position of the Examiner that this release rate like many properties can be manipulated and derived from routine experimentation. As discussed above the ratio of polymeric film to unitary dosage overlaps the range of the instant claims (0.16:1). It is the position of the Examiner that these specific ratios represent an optimized result determined through routine experimentation and do not impart patentability on the claims.

7. With the things in mind it would have been obvious to one of ordinary skill in the art to follow the suggestions of the art to follow the teachings and suggestions of the art in order to provide a stable combination therapy useful in treating various disorders. One of ordinary skill in the art would have been motivated to follow these teachings with an expected result of a combination therapy useful in treating various disorders.

(10) Response to Argument

Applicant argues that:

1). Johnson fails to show each and every element of the instant claims and therefor there is no prima facie case of obviousness.

Art Unit: 1618

2) The Examiner fails to comprehend that Johnson discloses two separate dosage form embodiment.

3) The Examiner fails to understand the structural features of the dosage form described in Johnson.

Regarding argument 1), it remains the position of the Examiner that the Johnson patent continues to obviate the instant claims. As discussed above the Johnson patent discloses a method of manufacturing a pharmaceutical tablet comprising dispersing a drug in a solid matrix such as pseudoephedrine; depositing on the surface of the unitary body a polymeric film that is devoid of a drug; depositing over the film coated unitary body a solution comprising a second drug and evaporating the liquid carrier from the drug solution. This method of manufacture is disclosed in Examples 1 and 2 where pseudoephedrine is dispersed in a matrix comprising celluloses. The solid matrix is coated with a film coating devoid of the core drug and comprising polyvinyl alcohol (col. 9, lin. 25) meeting the limitations of claim 4. This coated unitary matrix is further coated with a solution comprising a second drug cetirizine, where the water is removed. This final tablet comprises a first drug that is release in an immediate release fashion and a second drug released in a prolonged release fashion (Examples 1 and 2, col. 7, lin. 33-35). Claim 1 recites that the polymeric film prevents interaction between the first and second drug. The polymeric film of the Johnson patent is disclosed as impermeable to the core drug no allowing it to transmit through the polymeric film coating, effectively preventing interaction between the first and second drugs meeting the limitations of the claims 1 (col. 8, lin. 50-col. 9, lin. 8). The deposited polymeric film can further comprise pore forming agents which would dissolve meeting the limitations of claim 1. Applicant argues that the polymer membrane does

Art Unit: 1618

not dissolve in gastrointestinal fluid, however ignores the pore forming components that are included in the polymeric film that would dissolve. As the claims do not recite a dissolution or disintegration rate, any dissolution anytime after ingestion would meet the limitation of the claims. The pore forming agents are incorporated into the polymeric film and would dissolve in the GI tract leaving pores (col. 10, lin. 35-45). Further Applicant argues that the polyvinyl alcohol of the instant claims is somehow different from the polyvinyl alcohol disclosed in the Johnson patent. Applicant argues that differences in molecular weight, crosslinking, etc. would render the polymer dissolvable and since these factors are not mentioned the polymeric film of the Johnson patent cannot dissolve. However Applicant is arguing elements and features that are not present in the instant claims. The claims recite that polymeric film is comprised of polyvinyl alcohol. The polymeric film of Johnson can comprise polyvinyl alcohol (col. 9, lin. 25).

Regarding the "prolonged" release of the inner second drug, the Johnson patent discloses that the pseudoephedrine is release in a sustained fashion, metering out its contents over a 4 to 36 hour period (col. 3, lin. 10-26). 75% of the drug is release in a period from 4 to 36 hours, meeting the limitation of claim 1. Applicant argues that the unitary core of the Johnson patent is "incapable of providing prolonged release", yet provides no evidence to support such allegations. The solid matrix core of the instant claims is defined by its constituents, which comprise a Markush group of polymers such as hydroxypropylmethyl cellulose, which is disclosed as a component of the Johnson matrix (col. 7, lin. 5-30). The release profile of the instant claims is a functional limitation defined by the compositional components. The Johnson patent provides a solid unitary dosage form comprising the identical compositional components as the instant claims. As such the solid matrix dosage form would be expected to posses the same functional imitations

Art Unit: 1618

as the instant claims. Applicant has provided no evidence to the contrary. In conclusion the Johnson patent provides a method of manufacturing a solid tablet obvious over the instant claims. The resulting tablet would release 75% of its inner drug from a period from 4 to 36 hours. The method comprises dispersing a drug within a solid matrix, depositing over said matrix a polymeric film devoid of the drug, and depositing over said coated dosage form a film layer comprises a different drug releasable in an immediate release. The Johnson patent discloses the same polymers present in the solid matrix core, polymeric film. The film has the same features as the instant claims such as not allowing interaction between the drugs and some degree of dissolution in the GI tract. These disclosures obviate the instant claims.

Regarding argument 2) Applicant argues that is "simply incorrect" to assume that Johnson discloses a sustained release core surrounded by a drug free intermediate layer. Applicant is directed to Example 1 and 2, where a solid matrix tablet comprising a first drug is coated with a drug free membrane coating. The Examiner does not deny that multiple embodiments are presented in the Johnson patent, however in the singular embodiments of Example 1 and 2, solid unitary cores comprising dispersed drugs are coated with drug free intermediary layers. The layers in the Examples differ from the instant claims, however one of ordinary skill in the art would be able to substitute any of the listed polymers and determine further iterations of the formulation through routine experimentation.

Regarding argument 3) Applicant argues that polyvinyl alcohol of the Johnson polymeric film cannot dissolve in gastrointestinal fluid. Applicant further argues that the film of the Johnson patent will not dissolve in gastrointestinal fluid. Applicant notes that the polyvinyl alcohol is listed as a water-insoluble polymer and as such cannot dissolve in the gastrointestinal

Art Unit: 1618

fluid. Applicant apparently requires a much more narrow reading of the instant claims. The instant claims require that the polymeric film is formed from a polymer and dissolves in gastrointestinal fluid. However the claim does not requires that the polymer dissolve in gastrointestinal fluid. The film must dissolve in gastrointestinal fluid and as such the disclosures of pore forming components, which are incorporated into the film and would meet the limitations of the claim. For these reasons the claims remain obviated.

(11) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

/MICAH-PAUL YOUNG/

Examiner, Art Unit 1618

Conferees:

/MICHAEL G. HARTLEY/

Supervisory Patent Examiner, Art Unit 1618

/Frederick Krass/

Supervisory Patent Examiner, Art Unit 1612